

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	
)	MDL NO. 1203
)	
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THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203
)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8967

Bartle, J.

November 15, 2012

Greta B. Wadlington ("Ms. Wadlington" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Richard L. Wadlington, Ms. Wadlington's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In December, 2002, Ms. Wadlington submitted a completed Green Form to the Trust signed by her attesting physician, Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Dr. Evans is no stranger to this litigation. According to the Trust, he has signed in excess of 300 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated June 13, 2001, Dr. Evans attested in Part II of Ms. Wadlington's Green Form that she suffered from moderate mitral regurgitation

3. (...continued)
medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

and a reduced ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$528,405.⁴

In the report of claimant's echocardiogram, the reviewing cardiologist, David P. Hall, M.D., stated that "[t]here is mild [mitral regurgitation]." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view, is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Hall also opined that "[t]he overall [left ventricular] function seemingly is within normal limits, in excess of 60%."⁵ An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id. § IV.B.2.c.(2)(b)iv).

In March, 2004, the Trust forwarded the claim for review by Charles Pollick, M.D., one of its auditing cardiologists. In audit, Dr. Pollick concluded that there was no

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). A reduced ejection fraction is one of the complicating factors needed to qualify for a Level II claim.

5. Claimant also submitted an echocardiogram report prepared by Dr. Evans in November, 2002 based on her June 13, 2001 echocardiogram. In this report, Dr. Evans stated, "There is moderate mitral regurgitation. The RJA:LAA ratio is 30%." Dr. Evans also opined that the "[left ventricular] ejection fraction is calculated to be 60%."

reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. Dr. Pollick stated that "[mitral regurgitation] in the [parasternal long-axis] view is a thin jet [approximately] 2.5 cm long and a tear drop shape max width [of] 1 cm. In the [apical four-chamber] view the jet is clearly less than 20% of the [LAA]. Therefore the [mitral regurgitation] is mild." Dr. Pollick also concluded that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction, explaining that "[t]he [ejection fraction] is clearly above the settlement agreement determined standard of normality."

Based on Dr. Pollick's findings, the Trust issued a post-audit determination denying Ms. Wadlington's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted affidavits from Dr. Evans and Dan A. Francisco, M.D., F.A.C.C. In his affidavit, Dr. Evans confirmed his previous findings, and stated that the echocardiogram showed "'moderate' mitral valve regurgitation with a RJA/LAA ratio in excess of 20%." Dr. Evans further stated that

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Wadlington's claim.

"[b]ased upon my visual assessment, the ejection fraction is between 50-60%. It is not over 60%." Dr. Francisco also opined that claimant's echocardiogram demonstrated "'moderate' mitral valve regurgitation with a RJA/LAA ratio of 26%" and "an ejection fraction of 59%". Claimant argued, therefore, that she had established a reasonable medical basis for her claim because two Board-Certified cardiologists independently agreed that she had moderate mitral regurgitation and a reduced ejection fraction. Claimant further asserted that the auditing cardiologist "apparently did not understand the difference between his personal opinion ... and the 'reasonable medical basis' standard." (Emphasis in original.)

The Trust then issued a final post-audit determination, again denying Ms. Wadlington's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Wadlington's claim should be paid. On May 20, 2005 we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5242 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a Reply on August 4, 2005, and

claimant submitted a sur-reply on September 1, 2005. Under the Audit Rules it is within the Special Master's discretion to appoint a Technical Advisor⁷ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation and a reduced ejection fraction in the range of 50% to 60%. See id. Rule 24. Ultimately if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement.

See id. Rule 38(b).

In support of her claim, Ms. Wadlington reasserts the arguments she made in contest; namely, that the opinions of Dr. Evans and Dr. Francisco establish a reasonable medical basis for finding moderate mitral regurgitation and a reduced ejection fraction. In addition, claimant argues that the concept of inter-reader variability accounts for the differences between the opinions of Dr. Evans and Dr. Francisco and the opinion of the auditing cardiologist, Dr. Pollick. More specifically, claimant asserts that there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, Ms. Wadlington contends that if the Trust's auditing cardiologist or a Technical Advisor concludes that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA ratio by an attesting physician is medically reasonable. Similarly, claimant asserts that there is also an "absolute" inter-reader variability of 18% when evaluating an ejection fraction using Simpson's Method, 16% when using wall motion index, and 19% when using subjective visual assessment. Thus, there would be a reasonable medical basis for the attesting physician's finding of an ejection fraction of 60% if the auditing cardiologist or the Technical Advisor measured the ejection fraction to be as high as 79%.

In response the Trust argues that the opinions of Dr. Evans and Dr. Francisco do not establish a reasonable medical

basis for the claim because they fail to address the specific findings of the auditing cardiologist. The Trust also notes that neither Dr. Evans nor Dr. Francisco addresses the original echocardiogram report prepared by Dr. Hall, which concludes that Ms. Wadlington had only mild mitral regurgitation and a normal ejection fraction. Finally, the Trust contends that claimant's inter-reader variability argument cannot "explain away Dr. Pollick's conclusion that the Attesting Physician's Green Form representations ... are without any reasonable medical basis."

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Vigilante found that:

Visually, the degree of mitral regurgitation appeared mild in the parasternal long axis and apical four chamber views. There were no views of the mitral regurgitation in the apical two chamber view. The mitral regurgitation appeared to be a short and posteriorly directed jet in the parasternal long axis view. The [mitral regurgitation] jet was more laterally displaced in the apical four chamber view.... The RJA/LAA ratio was less than 17% in those views in which the mitral regurgitation jet appeared most severe. The RJA/LAA ratio never came close to approaching 20%. Most of the cardiac cycles demonstrated RJA/LAA ratios less than 15%.

Dr. Vigilante also determined that there was no reasonable medical basis for the attesting physician's finding of a reduced ejection fraction. He stated:

Visually, the left ventricular ejection fraction appeared to be approximately 65% when evaluated in the parasternal long axis, parasternal short axis, apical four chamber, and apical two chamber views.... I then traced the endocardium of the left ventricle in end systole and end diastole and calculated the ejection fraction. The ejection fraction was between 64 and 66% in these cardiac cycles. The [ejection fraction] was never close to 60%.

After reviewing the entire Show Cause record, we find claimant's arguments are without merit. First, claimant does not adequately refute the specific conclusions of the auditing cardiologist and the Technical Advisor. She does not challenge the auditing cardiologist's determinations that the mitral regurgitant jet was mild with "a thin jet [approximately] 2.5 cm long and a tear drop shape max width [of] 1 cm," and that the ejection fraction was 65%.⁸ Nor does she contest the Technical Advisor's determinations that "[t]he RJA/LAA ratio was less than 17% in those views in which the mitral regurgitation jet appeared most severe," and that "[t]he [ejection fraction] was never close to 60%."⁹ Although Ms. Wadlington submitted affidavits from two cardiologists, neither claimant nor her experts identified any

8. For this reason as well, we reject claimant's argument that the auditing cardiologist simply substituted his opinion for the diagnosis of the attesting physician.

9. Despite the opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

specific errors in the conclusions of the auditing cardiologist and the Technical Advisor. They also do not explain the reviewing cardiologist's determination that claimant's echocardiogram demonstrated only mild mitral regurgitation and a normal ejection fraction. Mere disagreement with the auditing cardiologist or the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

Claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Wadlington had moderate mitral regurgitation is misplaced. The concept of inter-reader variability already is encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the auditing cardiologist and the Technical Advisor concluded that claimant's RJA/LAA ratio was "clearly less than 20%" and "was less than 17%," respectively. In addition, the reviewing cardiologist determined that claimant's echocardiogram demonstrated only mild mitral regurgitation. Adopting claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation by $\pm 15\%$ would allow a claimant to recover Matrix Benefits with an

RJA/LAA ratio as low as 5%. This result would render meaningless this critical provision of the Settlement Agreement.¹⁰

We also are not persuaded by claimant's assertion that the difference in opinion regarding her ejection fraction is also due to inter-reader variability. The auditing cardiologist and the Technical Advisor found claimant's ejection fraction to be approximately 65%, and the reviewing cardiologist determined claimant's ejection fraction was "in excess of 60%." Adopting claimant's argument that inter-reader variability expands the range of her ejection fraction by as much as $\pm 19\%$ would allow a claimant to recover Matrix Benefits with an ejection fraction as high as 79%. This result would also be inconsistent with the requirements of the Settlement Agreement.¹¹

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation and a reduced ejection fraction. Therefore, we will affirm the Trust's denial of Ms. Wadlington's claim for

10. Moreover, the Technical Advisor took into account the concept of inter-reader variability as reflected in his statement that "[a]n echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability."

11. In addition, the Technical Advisor took into account the concept of inter-reader variability. He stated, "An echocardiographer could not reasonably conclude that an ejection fraction of 50%-60% was present on this study even taking into account inter-reader variability."

Matrix Benefits and the related derivative claim submitted by her spouse.